

**OPTN Data Advisory Committee
Meeting Summary
August 12, 2024
Conference Call**

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Introduction

The OPTN Data Advisory Committee met via WebEx teleconference on 08/12/2024 to discuss the following agenda items:

1. Welcome, reminders, and agenda review
2. OPO Committee, Machine Perfusion Project first check in
3. Lung Committee, Lung Donor Testing (part 2) first check in
4. Form revisions: Source of Payment
5. Additional Committee business
6. Public forum
7. Closing remarks

The following is a summary of the Committee's discussions.

1. Welcome, reminders, and agenda review

The Chair welcomed the members to the meeting and provided an overview of the agenda topics. As part of today's meeting, there are first check-ins from the OPTN OPO Committee and the OPTN Lung Transplantation Committee. The Committee is also going to discuss the proposed Source of Payment form revisions.

2. OPO Committee, Machine Perfusion Project first check in

The OPO Committee is proposing a project to centralize machine perfusion data collection and track Normothermic Regional Perfusion (NRP) data. The proposed data solution involves adding additional data collection points and revising current data collection forms. The OPO Committee is presenting the information to the Committee for the first time and requests endorsement of the proposed data collection. The project will be presented to the OPTN Policy Oversight Committee for approval on 09/12/2024.

Summary of discussion:

Decision #1: The Committee endorsed the OPTN OPO Committee's proposed data collection effort.

The presentation provided an overview of the OPO Committee's proposal to centralize machine perfusion data collection and track NRP data. The presenter stated that the OPO Committee expects this to be a rather large project which will require the collaboration of many OPTN committees. The presenter added that there are now many perfusion machines available across the organs, as well as thoracoabdominal normothermic regional perfusion (TA-NRP). As a result, a lot of data are being collected through multiple OPTN data collection tools. The proposed data solution involves adding additional data collection points and revising current data collection forms. Ultimately, the changes are

intended to create a comprehensive and consistent data collection effort, as well as to develop some requirements for documenting these types of cases. The project aligns with developing transplant policies, ensuring patient safety, and may lead to policy changes. The proposed timeline includes check-ins, public comment, and board approval by December 2025.

The presenter shared with the Committee members the data elements that the OPTN Board of Directors has approved for collection, and said the elements will need to be reviewed to determine if they are still appropriate for collection. It was pointed out that quite a few data elements will need to be added to the current system. The presenter said that with the advances in technology, transplant programs can travel farther to procure an organ, but at the same time, ensuring patient safety is critical; nonetheless, a lot of information that is needed to address such considerations is not collected or is not collected in a comprehensive and consistent manner.

The OPO Committee hopes to present the project idea to the OPTN Policy Oversight Committee in September. The OPO Committee expects to present revised information to the Data Advisory Committee in May 2025 before submitting a proposal for public comment. Depending on the public comment feedback, the OPO Committee could provide another presentation to DAC following public comment and before submitting a proposal to the OPTN Board of Directors. Initial discussions with OPTN contractor staff have occurred to better understand the current data collection flow in the OPTN computer system, as well as how the DCD and NRP recovery processes might impact data collection. It was also mentioned that two DAC members have agreed to join the Machine Perfusion Data Collection workgroup.

The DAC Chair thanked the OPO Committee representative for the presentation. The Chair acknowledged the importance associated with understanding the impact of such technologies. The Chair also said this represents a very important use case, not only for new data collection, but for trying to be as timely and contemporary as possible with current technologies. It was pointed out that even under the most streamlined circumstances, the collection of any new data for this project would not be until the beginning of 2026 even though this is a technology which has been used for a couple of years and is affecting transplant dramatically, and something the OPTN wants to understand for patient safety and outcome reasons. The Chair stated that it would be nice to think about a pathway that could expedite at least the basic data collection being proposed. A Committee member agreed with the Chair's comments about timeliness, and asked about when the OPO Committee would schedule the second DAC check-in? The member also stated that ASTS recently published recommendations for data collection and asked if the OPO Committee saw an opportunity for collaboration there? The OPO Committee representative said they would share the idea of such a collaboration or partnership with ASTS with the full committee. The member also said that it is going to be very important to develop definitions for the data elements, so it is clear exactly what each element means, the timeframes the data are to be collected within, and which OPTN collection tools will be used.

The Chair also asked whether it would be possible to identify where the OPTN has already collected some of the data and then use that information to help augment what will be collected moving forward.

There was discussion about the information that is already collected, as well as data collection projects that have been approved by the OPTN Board but have not been implemented. The OPO representative mentioned that their committee is still waiting for OMB approval of some data elements that would help jump start the larger collection effort. It was also mentioned that perfusion technology is going to keep evolving; therefore, the OPTN needs to be nimble enough to change and adapt in terms of data collection associated with new technological changes. It was mentioned that the OPTN Board approved data collection that has not been implemented is one of several projects that are still awaiting OMB approval before they can be implemented. HRSA has decided to hold those projects and incorporate

them with the pre-waitlist and ventilated patient data collection efforts identified in the HHS Directive; however, the Directive effort has not moved forward to date.

A Committee member asked what steps are being taken to identify the information already being collected by transplant programs in order to help determine what should be collected in the future. The presenter said the project is working to identify that information.

The Committee members requested that the OPO Committee provide another presentation prior to submitting a proposal for public comment. The presentation should provide an update about the project's status and describe how the OPO Committee addressed the members' questions and comments. A member asked that the OPO Committee try to keep the electronic medical record vendors aware of the project and any proposed changes.

The Chair asked if there were any members opposed to DAC's endorsement of the data collection aspects of the OPO Committee's project. None of the members indicated opposition.

Next steps:

The OPO Committee presenter said the member's feedback will be share with the committee and the Machine Perfusion Data Collection workgroup. They also said they will check-in again with DAC when more information is available to share.

3. Lung Committee, Lung Donor Testing (part 2) first check in

The OPTN Lung Transplantation Committee is starting a project to continue promoting efficiency opportunities within lung continuous distribution with an emphasis on the data collection being performed by OPOs and transplant programs.

Summary of discussion:

Decision #1: The Committee endorsed the OPTN Lung Transplantation Committee's proposed data collection effort.

The OPTN Lung Transplantation Committee is considering adding new data fields to improve efficiency and accuracy in lung allocation. The Lung Committee's idea is to improve efficiency in lung allocation for both OPOs and transplant programs by making it easier for lung transplant programs to say yes to organ offers. The change may impact data collection in several ways, including collection of additional data elements to help make informed decisions about lung offers. The proposal will also seek to improve the accuracy and increase the granularity of the information currently collected.

Proposed new data fields include predicted total lung capacity, peak inspiratory pressure, and specific smoking and vaping history. The DAC Chair pointed out that with one exception, OPOs already collect this information; however, it is not currently collected by the OPTN. The exception is the predicted total lung capacity data field, but that is actually a calculated value based on data already collected by the OPTN. The Lung Committee also aims to update current data collection fields to increase granularity and improve the evaluation of lung offers. The proposed data collection changes are also intended to reduce the back-and-forth conversations between OPOs and transplant programs about donor organ information; thus, further promoting system efficiency. The data collection changes will impact components of the OPTN computer system and the associated data collection tools.

Several Committee members provided feedback to the presenter. A DAC member asked if the Lung Committee had considered or was proposing the removal of any data elements in light of the proposed additions? The presenter said that the current data element addressing cigarette smoking of over/under

20 packs a year will be replaced. However, the Lung Committee had not comprehensively reviewed whether other, perhaps non-related, data elements could be removed. The DAC Chair recommended that the Lung Committee strongly consider eliminating the use of “Other” as a legitimate reporting option because it leads to ambiguity in the results. The Lung Committee presenter indicated a shared concern about the lack of specificity associated with “Other.”

Other suggestions made by DAC members included:

- Exploring how the changes might impact standard practice of how data is currently collected in the Electronic Health Records (EHR), and how system mapping might change as a result
- Exploring options for collecting retrospective data
- Discussing the feasibility and relevance of capturing historical information about a donor’s use of other inhalants
- Exploring the capture of marijuana and vaping history in a more specific and accurate way
- Considering removal of the “over/under 20 packs per year” field for cigarette smoking history and replacing it with actual pack years

The Chair asked if there were any members opposed to DAC’s endorsement of the data collection aspects of the Lung Committee’s project. None of the members indicated opposition.

Next steps:

The presenter said that the Lung Committee’s collaboration with DAC will involve regular check-ins and updates on refined solutions.

4. Form revisions: Source of Payment

The Committee discussed proposed changes to the Source of Payment field and choice list options. The changes aim to improve data collection and eliminate the “unknown” option for better accuracy.

Summary of discussion:

Decision #1: The Committee endorsed the proposed changes to the Source of Payment data field and choice list options

OPTN contractors staff provided background information about the discussion topic. The request for changes came from an OPTN member organization asking for help on how to document the Medicare Advantage plan on the Source of Payment fields. DAC’s Holistic Data Review Workgroup provided feedback, along with the OPTN Pediatric Committee. Contractor staff said the Committee is being asked to endorse the modifications as a non-substantive change to OPTN data collection. As a result, making the changes will not require a policy project.

Contractor staff stated that proposed changes only impact the options where clarifications are needed. For example, ‘Private insurance’ will be changed to ‘Private insurance (Commercial Health Insurance),’ and ‘Public insurance – Medicare & Choice’ will be changed to ‘Public insurance – Medicare Part C or Medicare Advantage.’ Furthermore, the option ‘Public insurance – Other government’ will be split into three options: i) Public insurance – TRICARE; ii) Public insurance – Indian Health Service; and iii) ‘Public insurance – State program.’ Public insurance – State program will only appear for pediatric candidates as was requested by the OPTN Pediatric Committee. In addition, the ‘unknown’ option will be removed and several OPTN committees agreed with removing the option. OPTN contractor staff added that based on previous Committee discussions, the secondary source of payment data collection fields have been retired. As a result, there is no longer a need to update that choice list option.

The Chair asked which current OPTN data collection tools the changes will be modified as a result of the proposed changes. OPTN contractor staff said the candidate-specific and recipient-specific collection tools are impacted. In response to a member question, OPTN contractor staff said that employer-based insurance would be accounted for through the commercial health insurance option. A member suggested making similar modifications for donor insurance fields to ensure consistency and OPTN contractor staff agreed to consider the suggestion. Another member recommended updating form instructions and communication avenues to ensure appropriate dissemination of the proposed updates. It was also recommended that mapping issues involving the Medicare Advantage and Unknown choice options be discussed with EMR vendors.

The Chair asked if there were any members opposed to DAC's endorsement of the proposed updated to the primary source of payment data element and choice options. None of the members indicated opposition.

Next steps:

OPTN Contractor staff will work to notify the EMR vendors about the modification before implementation.

5. Additional Committee business

Members were asked to review the slides asking them to update the information about how they interact with OPTN data, among other data-specific activities. The information is maintained in a spreadsheet on the Committee's SharePoint site and the responses help OPTN contractor staff identify who to contact for assistance with form revisions and workgroup membership requests. The slides also provide information about a request for DAC members to join a workgroup being formed by the OPTN Operations and Safety Committee concerning their new project, *Re-evaluation of Deceased Donor Testing Requirements*. OPTN contractor staff also informed members that there are slides about the on-going OPTN regional meetings included in the presentation. OPTN contractor staff also let members know that the regional meetings include an update from HRSA staff about the status of the data directive, among other information, and an update about the on-going activities of the OPTN Expedient Task Force.

6. Public forum

There were no requests to speak during this part of the meeting.

7. Closing remarks

Members were reminded to book their travel to Detroit for the Committee's in-person meeting scheduled for 09/10/2024. There is a Committee dinner the night before the meeting for the members attending in-person. The Chair thanked the members for participating in today's meeting.

Upcoming Meetings (Meetings start at 3:00 pm (ET) unless otherwise noted)

- July 8, 2024
- August 12, 2024
- September 10, 2024 – In-person meeting, Detroit, MI, 8:00 am – 3:00 pm (ET)
- October 21, 2024
- November 18, 2024
- December 9, 2024
- January 12, 2025
- February 10, 2025

- March 10, 2025
- April 14, 2025
- May 12, 2025
- June 9, 2025

Attendance

- **Committee Members**
 - Jesse Schold
 - Lisa McElroy
 - Rebecca Baranoff
 - Kate Giles
 - Cassie Hertert
 - Michael Ison
 - Michael Marvin
 - Christine Maxmeister
 - Nancy McMillan
 - Jennifer Peattie
 - Julie Prigoff
 - Alicia Skeen
 - Allen Wagner
- **HRSA Representatives**
 - Brianna Doby
 - Steve Keenan
- **SRTR Staff**
 - Avery Cook
 - Ajay Israni
 - Jon Snyder
- **UNOS Staff**
 - Brooke Chenault
 - Jonathan Chiep
 - Cole Fox
 - Sevgin Hunt
 - Robert Hunter
 - Eric Messick
 - Tatenda Mupfudze
 - Kelley Poff
 - Nadine Rogers
 - Laura Schmitt
 - Kaitlin Swanner
 - Susan Tlusty
 - Kimberly Uccellini
- **Other Attendees**
 - Matt Hartwig
 - Lori Markham